UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/822,949	04/13/2004	Rong-Kun Chang	063089-0129	3599

22428 7590 08/01/2008
FOLEY AND LARDNER LLP
SUITE 500
3000 K STREET NW
WASHINGTON, DC 20007

EXAMINER	
FUBARA, BLESSING M	

ART UNIT	PAPER NUMBER
1618	

MAIL DATE	DELIVERY MODE
08/01/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/822,949	CHANG, RONG-KUN	
	Examiner	Art Unit	
	BLESSING M. FUBARA	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 April 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5 and 7-15* is/are pending in the application.

4a) Of the above claim(s) *8-13* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5, 7,14 and 15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Examiner acknowledges receipt of amendment and remarks filed 4/24/08. Claim 6 is canceled. Claim 1 is amended. Claims 1-5 and 7-15 are pending; claims 8-13 are withdrawn form consideration.

Status Identifiers:

Claims 8-13 are not accorded appropriate status identifiers as required by MPEP 714 [R-6], II CA, on the "MANNER OF MAKING AMENDMENTS UNDER 37 CFR 1.121" which states that "Each amendment document that includes a change to an existing claim, including the deletion of an existing claim, or submission of a new claim, must include a complete listing of all claims ever presented (including previously canceled and non-entered claims) in the application. After each claim number, the status identifier of the claim must be presented in a parenthetical expression, and the text of each claim under examination as well as all withdrawn claims (each with markings if any, to show current changes) must be presented. The listing will serve to replace all prior versions of the claims in the application.

(A) Status Identifiers: The current status of all of the claims in the application, including any previously canceled or withdrawn claims, must be given. Status is indicated in a parenthetical expression following the claim number by one of the following status identifiers: (original), (currently amended), (previously presented), (canceled), (withdrawn), (new), or (not entered). The status identifier (withdrawn – currently amended) is also acceptable for a withdrawn claim that is being currently amended. See paragraph (E) below for acceptable alternative status identifiers.

Claims added by a preliminary amendment must have the status identifier

(new) instead of (original), even when the preliminary amendment is present on the filing date of the application and such claim is treated as part of the original disclosure. If applicant files a subsequent amendment, applicant must use the status identifier (previously presented) if the claims are not being amended, or (currently amended) if the claims are being amended, in the subsequent amendment. Claims that are canceled by a preliminary amendment that is present on the filing date of the application are required to be listed and must have the status identifier (canceled) in the preliminary amendment and in any subsequent amendment. The status identifier (not entered) is used for claims that were previously proposed in an amendment (e.g., after-final) that was denied entry.

Applicant is reminded of the manner of making amendment according to MPEP 714 [R-6], II CA.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-3, 5, 7 and 14 remain rejected under 35 U.S.C. 102(b) as being anticipated by Faour et al. (US 6,004,582) for reasons of record and reiterated herein below with accommodation for amendment to claim 1 incorporating the limitations of claim 6.

Faour discloses a multi-layered delivery device (abstract), that is "useable in different environments for use of the osmotic device include biological environments such as the oral,

ocular, nasal, vaginal, glands, gastrointestinal tract, rectum, cervical, intrauterine, arterial, venous, otic, sublingual, dermal, epidermal, subdermal, implant, buccal, bioadhesive, mucosal and other similar environments. Likewise, it may be used in aquariums, industrial warehouses, laboratory facilities, hospitals, chemical reactions and other facilities" (column 4, lines 34-42). The dosage form is in the form of a tablet, pill, sphere, bar, plate or granule (column 6, line 7). The core of the tablet can comprise a number of agents such as osmagents, buffering agents, antioxidants, acacia, alginic acid, polyvinylpyrrolidone, methylcellulose, polyethylene glycol and many more that used with active agents in tablet formulation (column 9, line 28, 38-65; column 10, lines 14-57) and these materials used in the core or matrix of tablets meet the polymer requirements of claim 2. The multi-layered nature of the dosage form meets claim 3. Claim 5 describes the properties of the dosage form. The limitation of claim 6, now incorporated into claim 1 is directed to the property of the composition and in the same way, the recitation that the composition "is not absorbed through the oral mucosa to a substantial extent is a property of the composition. The process of preparation of the dosage form is exemplified in at least Examples 1-4 and method claim 14 read on Faour's method. Faour formulates a number of active agents as multilayered tablets (column 13, line 38 to column 16, line 44) and included in this list is riboflavin (column 16, line 31) with the teaching of the riboflavin meeting claim 7.

Response to Arguments

3. Applicant's arguments filed 4/24/2008 have been fully considered but they are not persuasive.

4. Applicant argues that the Faour does not teach each and every limitation of the claimed invention because the "current invention" is a buccal or sublingual dosage form where the active

agent is not absorbed through the oral mucosa to a substantial extent, but the active agent is gradually released over an extended period and that the active agent, once released is swallowed and absorbed in the gastrointestinal tract.

5. The examiner disagrees. a) the invention is directed to a sustained release pharmaceutical dosage form and the dosage form of Faour is a sustained release dosage form; b) holding the sustained delivery dosage form in a buccal or sublingual location is the intended route of administration and the dosage form of Faour is intended for oral or buccal administration and when administered orally or through the buccal cavity, the dosage form is resident in the buccal or oral cavity for a time such that when a release occurs in the buccal cavity as applicant asserts, the active agent released is inherently swallowed for absorption in the gastrointestinal tract because Faour is clear that the active agent(s) is released in the stomach and in the intestines (column 5, lines 39 and 45). c) Although applicant states that Faour teaches an osmotic device that delivers active agent "to benefit the environment of use" that includes sublingual and buccal environments where the active agents are absorbed into the local sublingual and buccal environments, applicant acknowledges that there are other dosage forms of Faour that have active agents that are intended to be active in different local environments further acknowledging Faour's teaching that the active agent is released in the stomach and the intestines (column 5, lines 39 and 45). d) Furthermore, it is noted that because Faour teaches the sustained release dosage form of the claims, it flows that the dosage forms of Faour would be capable of being held in the oral/buccal cavity for release and absorption in the stomach and intestines (gastrointestinal tract).

6. Claims 1, 2, 4, 5, 7, 14 and 15 remain rejected under 35 U.S.C. 102(b) as being anticipated by Lerner et al. (US 6,197,331) for reasons of record and reiterated herein below with accommodation for amendment to claim 1 incorporating the limitations of claim 6.

Lerner discloses controlled release solid composition for the oral cavity or pharmaceutical oral patch (abstract) with the disc of claims 14 and 15 reading on the patch; the composition contains adhesive and release layer (column 8, lines 20-25) meeting the requirement for as layered dosage form in which one surface is adhesive, thus meeting claim 4 and another surface, non-adhesive (column 7, lines 53 and 54); polymer in the adhesive layer is EUDRAGIT type polymer (column 11, lines 24 and 25; column 7, lines 25-28, 45-50); the matrix can also contain plasticizers such as polyethylene glycol, castor oil (column 11, line 66 to column 12, line 5) with the polymer or the oil meeting claim 2. Lerner specifically teaches that "any agent can be used, depending on the purpose of therapy" (column 15, lines 12 and 13) and proceeds to name specific ones and cyclosporin is mentioned as a peptide or protein drug (column 16, lines 52-56) meeting claim 7. The mixing of the polymer with the active agent and eventually formulating the composition into patch (column 17, lines 26-34) meets the requirements of the method claims 14 and 15. The limitation of claim 6, now incorporated into claim 1 is directed to the property of the composition and in the same way, the recitation that the composition "is not absorbed through the oral mucosa to a substantial extent is a property of the composition. Lerner thus teaches all the limitations of the designated claims.

Response to Arguments

7. Applicant's arguments filed 4/24/08 have been fully considered but they are not persuasive.

8. Applicant says that Lerner does not teach every element of the claimed invention because the Lerner dosage form is designed to deliver pharmaceutical agent for local treatment of the oral cavity, throat and esophagus. But, while Lerner delivers to the oral cavity, Lerner also delivers to the esophagus as acknowledged by applicant in the remarks; the esophagus is not the oral cavity but the connecting tube between the mouth/oral cavity and the stomach; and it is inherent that that a swallowing action, may be responsible for delivery of the active agent to the esophagus. Therefore, the examiner disagrees that Lerner does not teach all each and every limitations of the claims. It is also noted that absorption to a substantial extent is relative especially when compared to Lerner and the contemplated delivery of active agent to the esophagus.

9. Claims 1, 2, 5-7 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Christenson et al. (US 3,065,143, provided by applicant on form PTO 1449).

Christenson discloses a tablet formulation containing doxylamine and hydrophilic polymer (column 1, lines 13, 14, 55-70; column 2, lines 19, 20; columns 7 and 8) and doxylamine is mentioned in example 6. Christenson teaches the limitations of the designated claims.

Response to Arguments

10. Applicant's arguments filed 4/24/08 have been fully considered but they are not persuasive.

11. Applicant argues that Christenson describes traditional pharmaceutical tablet, that is, one that is ingested via the gastrointestinal tract; that the gum gel barrier in the tablet of Christenson is described as being eroded by motion of the tablet in the gastrointestinal tract; and that for

theses reasons applicant argues, Christenson "cannot be held to teach a dosage form that might be held in the buccal or sublingual location." The examiner disagrees. Claim 1 is a product claim, with the product formulation having capacity of being held in a buccal cavity or sublingual location. Because the dosage form of Christenson is an oral dosage form, administered orally and having the same ingredients as the claimed composition, it has the capability to being held in the buccal or sublingual location. Further, the ability of the gum gel barrier of the tablet to be worn by the motion of the tablet in transit through the gastro-intestinal tract is what is happening to the tablet en route to through the GI tract and this does not deny the tablet of Christenson from being an oral dosage form comprised of medicament, polymer. Therefore, the rejection is not overcome and the rejection is maintained.

No claim is allowed.

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BLESSING M. FUBARA whose telephone number is (571)272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

/Blessing M. Fubara/
Examiner, Art Unit 1618